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Ethical Issues Regarding the Donation and Source of Cells for Tissue Engineering: A European Focus Group Study

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This article is part of the EuroSTEC project, which aims at developing tissue engineering-based treatments for structural disorders present at birth. EuroSTEC is positioned at the intersection of three areas with their own ethical issues: (1) regenerative medicine, (2) research with pregnant women and fetuses, and (3) research with neonates. Because of the link between these three areas in this project, one can expect to be confronted with new ethical challenges. To be able to respond adequately and timely to current and possible future ethical issues, a prospective and anticipatory ethical analysis is essential. To obtain a first impression of the ethical issues that might arise during the different phases of the project, a Delphi method was used. On the basis of the results of two previous rounds of questionnaires, two topics were selected for discussion in focus groups: ethical issues associated with (1) source of cells and (2) donation. The results could be divided into three clusters: Tissue, Donor, and Scientist. Where the former two clusters roughly coincide with the results of the previous rounds, the third subject was entirely new but discussed by both groups: the role of the scientist in the tissue engineering process.

Introduction

EUROSTEC IS AN INTEGRATED PROJECT ON “Soft tissue Engineering for congenital birth defects in children.” Funded by the European Commission under the Sixth Framework Programme (FP6), it commenced on January 1, 2007. The project unites 15 partner organizations (10 research institutes and 5 companies) from nine European countries.¹

Recent developments in tissue engineering will be used to treat children with congenital structural disorders, such as spina bifida, urogenital defects, gastroschisis, diaphragmatic hernia, and esophageal atresia. The EuroSTEC project focuses on both maternal–fetal (or *in utero*) as well as neonatal interventions using tissue-engineered products. Part of the EuroSTEC project design is an extensive ethical analysis, which will focus on all three phases of the project—(1) fundamental (*in vitro*) research, (2) animal experiments, and (3) clinical trials—and will also look ahead to the application of soft tissue engineering in clinical practice.

In a previous study we conducted a survey of ethical issues that might arise during the course of the project.² A modified Delphi study—a systematic forecasting method consisting of multiple rounds—was used to question professionals who are directly involved in preclinical or clinical research on tissue engineering for congenital birth defects. Their views on possible moral issues throughout the course of the project were surveyed as a starting point. As is commonly done, we

modified the Delphi method and restricted the number of rounds to ensure a high response rate throughout the multiple rounds.^{3–5} The first two rounds yielded a number of ethical issues² that demanded further exploration.

For the fundamental research phase, two dominant categories of ethical issues emerged: ethical issues associated (1) with the donation and (2) with the source of the cells used (see Table 1 for a list of the ethical issues identified by Delphi participants).

Previous literature research⁶ also identified these two clusters of ethical issues for fundamental research in tissue engineering. However, research on tissue engineers’ own perspective on these issues was lacking. From the perspective of an empirically based ethics, the views of these professionals—all involved in the EuroSTEC project—are expressly relevant because they have practical experience in the day-to-day routine of tissue engineering research and carry responsibility for that practice. The central objective of this empirical study was to further explore tissue engineering experts’ views on the two topics.

Materials and Methods

Participants

Two groups of experts working in fundamental research within the EuroSTEC project were formed, with attention

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TABLE 1. ETHICAL ISSUES IN THE FUNDAMENTAL RESEARCH PHASE AS IDENTIFIED BY DELPHI PARTICIPANTS

Category	Topic
Source	The use of fetal cells
	The use of cells from neonates
	The use of fetal stem cells
	The use of excess tissue obtained through abortion
	The use of embryonic stem cells
Donation	The use of umbilical cord stem cells
	Privacy of the donor of tissue
	Informed consent of the donor of tissue
	The possible invasiveness of the procedure through which tissue is obtained
	Uncertainty about the ownership of donated tissue

paid to equal distribution of gender, country, and place of work (for group characteristics, see Table 2).

Focus group sessions

As a result of the first two rounds of the Delphi study, two dominant categories were identified with regard to the fundamental research phase²: "donation" and "source of cells." The first Delphi round focused on the identification of ethical issues by the participants and round two asked them to indicate the importance of the issues identified. The focus groups in the third round aimed at exploring why these issues were mentioned and deemed more or less important. Focus groups are a form of group interview that uses communication between research participants to its advantage in order to generate research data; the group interaction during the process is explicitly used as part of the method. The idea behind the method is that a group process enables participants to explore and clarify their views in ways that would be more difficult during a one on one interview.⁷

The sessions were held in April 2009. General methodology and procedure were first explained in a plenary session, after which both groups went to separate rooms. A hand out with the ethical issues previously mentioned and ranked in order of importance was distributed to the participants of each specific group. As an opening question, the focus group leader asked the focus group participants for their opinion on the ranking of the ethical issues. The discussion was led by two senior researchers (W.D. and P.v.d.B.) and lasted

approximately 1 h. The sessions were recorded with the consent of the participants to allow qualitative analysis.

Analysis

The recordings were transcribed and entered into Atlas-ti 5.2. The transcripts were coded using a grounded theory approach, in which the codes and codebook emerge from the data (as opposed to previously formulated hypotheses which are "tested" against data).⁸ The transcripts were coded by a primary analyst (A.O.), whereas a secondary analyst (W.D.) reviewed the transcripts with the assigned codes and the code book. Codes were then grouped into themes (or "families"), and subsequently grouped in clusters.

Results

The qualitative analysis yielded 58 codes, which were grouped into eight themes and subsequently clustered in three clusters: (1) Tissue (16 codes in two themes), (2) Donor (22 codes in three themes), and (3) Scientist (20 codes in three themes).

Cluster 1: Tissue

This cluster encompasses two themes: (a) Beginning of life and (b) Source material (Fig. 1).

Beginning of life. The theme of beginning of life was addressed in focus group 2 (discussing the source of cells). The group agreed that the main question in judging the moral acceptability of experimenting with certain cell types centers on the question of "what do we consider life?" Within this context, the group mainly delved into the differences in moral status of human embryonic stem cells (hESCs) and fetal cells. In the literature on ethical issues in tissue engineering, the use of hESCs is the ethical issue most frequently discussed.⁶ Still, only one participant had moral qualms about working with hESCs. That participant would decline working with hESCs personally, but did not have problems with others working with these cells.

Some participants referred to the use of hESCs as "killing a life," with one person explicitly referring to Catholic doctrine on the topic, others held a different view. In the words of one of the other participants: "[Y]ou can't [say] that they die because they never lived." Most of the participants seemed to consider the use of fetal cells ethically more problematic, referring to the possibility of injuring a fetus when taking a tissue sample. As one person put it: "[P]eople don't necessarily

TABLE 2. PARTICIPANT CHARACTERISTICS

		Focus group 1 donation (n=10)	Focus group 2 source of cells (n=11)
Gender (% male)		7 (70.0)	7 (63.6)
Working in country	Austria	2	3
	The Netherlands	2	5
	France	1	—
	Germany	2	1
	Sweden	3	2
Place of work (%)	University/hospital	7 (70.0)	8 (72.7)
	Industry	3 (30.0)	3 (27.3)

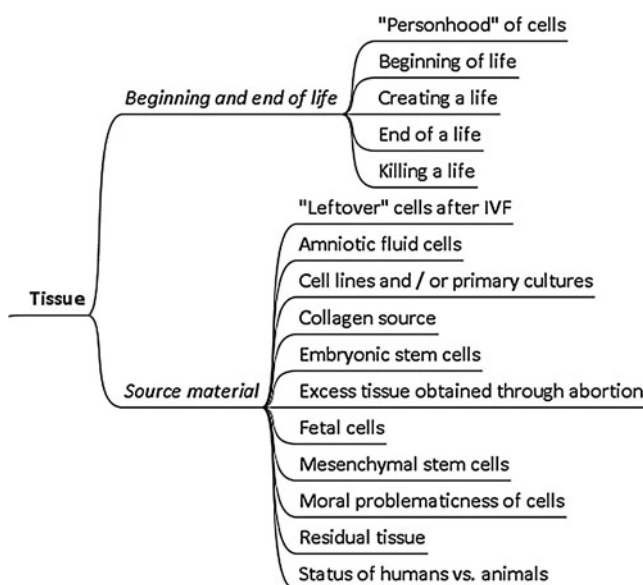


FIG. 1. Themes and codes for cluster "Tissue."

think that embryonic stem cells [...] would have the possibility of developing into an adult while fetal cells [...] come from the fetus which can potentially survive to be something."

Another participant referred to a difference in views between scientists and the general public, citing that where a scientist might view leftover embryos of *in vitro* fertilization (IVF) as a mere clump of cells, the general public sees it as new life and might judge their moral value differently.

Source material

The discussion of this theme overlapped with the previously discussed theme of the beginning of life. In discussing the complex issues of different sources of tissue engineering material, the deciding factor for most participants seemed to be the consequences for the donor of the sampled tissue, not necessarily the moral status of the source of the tissue. One of the participants noted it was not actually the nature of the cells that determined his moral judgment, but he instead considered the consequences of the "harvesting" of the cells in question the deciding factor in how ethically problematic the use of this tissue would be. For example, according to this argument cells that remained after IVF ("leftover") were less problematic than cells taken from a fetus, living *in utero*, through biopsy. He argued that he would have to look at the consequences ("what I am endangering") to make a final judgment on a case-by-case basis.

Cluster 2: Donor

This cluster was divided into three subthemes: (a) Control over use, (b) Helping, and (c) Miscellaneous (Fig. 2).

Control over use. All participants deemed control, or some say over their donated material, important for donors, especially when the purpose of its use is considered. According to the participants, the donated material should not be used for "bad" purposes without the donor's knowing; if a donor is told their material will be used for "good" re-

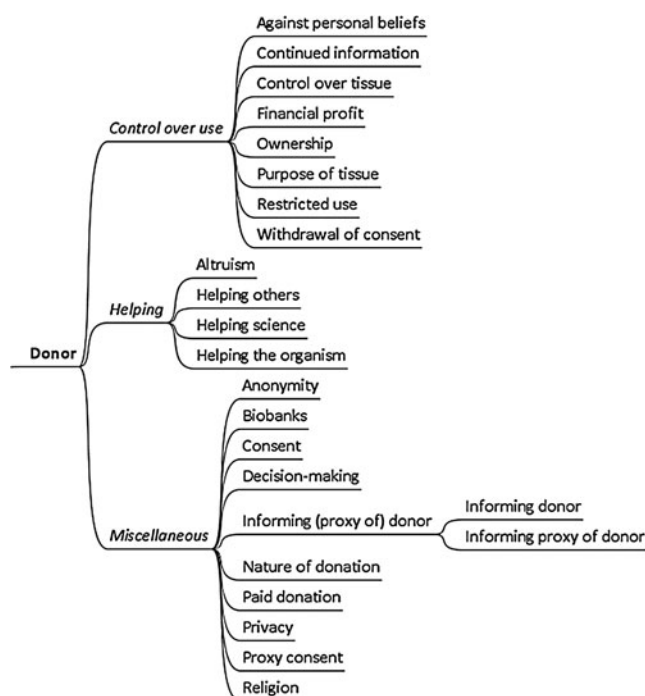


FIG. 2. Themes and codes for cluster "Donor."

search, their material should indeed be used for the purpose they were informed about and agreed to. As one participant put it: "Let's say if you agree to, with my donated tissue, to help children in need [...] then you want to know that this helped children in need. The specific child that is [...] helped might not be that important to you, but it could be that, okay, this is not for developing cosmetics for this cosmetics industry." Another said: "Suppose that the military would [want] to use it, to see the effect of some kind of bomb or whatever. I would definitely not like to have my skin be used for that."

An added difficulty is the removal of tissue from incompetent subjects and their inability to give consent. Several participants indicated that if they were to give proxy consent for the use of tissue from their children, they would restrict their consent solely to autologous use. Only when the child in question would reach the age of consent the material could be used for other purposes, and only if the child agreed. One participant was quite adamant about the question of ownership in this context: "This belongs to the child. 'Cause [...] for me there's no question of ownership. There's a fingerprint on the material that has been donated [by] the child. [I] as a parent just gave the opportunity [...] to donate, but what has been donated is not my property, even though I [gave] the permission."

Should donors be able to withdraw their consent? One participant said that that would not be a problem, and he would simply "go to [his] fridge, I would take his sample, I would take his slides, I would [...] discard the data from my Excel file and it's done." Others, however, saw this as a near impossibility; for instance, what should be done if data have already been published based on the material this person donated?

The question of the extent to which a donor should and can be informed about the future use of their donated sample

was thoroughly discussed. The way in which a scientist frames the question might heavily influence the likelihood of a prospective donor consenting. As one participant put it: "Are you willing to help people with cancer? Who wouldn't say yes to that question? But if they knew that this helping people with cancer would really be taking the cells, isolating the cells, cryopreserving them and multiplying them and spreading them all over the world, maybe they wouldn't be so helpful." Another participant added that it would be very difficult to specify exactly what donated tissue would be used for, because it often happens in tissue engineering, that the exact purpose is still unknown when one takes the sample.

Helping. Keeping in mind the difficulties that surround the process of donation as discussed in the context of the previous theme, the main motivation for donation was addressed: being able to help, be this helping oneself (in autologous donation), helping others, or being of benefit to science in general. In spite of possible obstacles or problems involved in donation, all participants agreed altruism is required to keep the scientific process of tissue engineering going. As one participant indicated, if there were no parents who gave consent to use their child's tissue, a large part of the research of this very project could not be done.

Miscellaneous. In addition to the two broader themes that were donor-related, several smaller topics received attention.

The achievability of full anonymity, one of the staples of the donating process, was questioned by the group; after all, in order to do research on a sample, characteristics like gender, race, and possible diseases are known to the researcher, which means that the sample might be traceable to a certain donor. Additionally, the balance between anonymity/privacy on the one hand and the previously discussed control over tissue on the other was deemed problematic. If one would be required to continue to supply a donor with information about the purposes of the use of parts of their material, then the repeated information requires that name and contact information would have to be known to someone, thereby encroaching on the ideal of anonymity and privacy.

In discussing possible motivations for donating, the topic of financial compensation came up. Several participants were adamant about their opposition to paid donation. One explained: "I would oppose it 100%. [...] It can induce all kinds of strange situations [in which people] are trying to make money if [they]'re poor, [...] doing things that are very unhealthy. So to protect people from themselves, I would say, I would oppose it."

Cluster 3: Scientist

The cluster "Scientist" consists of three themes: (a) Future of science, (b) Scientist and society, and (c) Scientist as person (Fig. 3).

Future of science. In discussing problems associated with the (proxy) consent process, several participants predicted that a stricter, more rigorous process might cause the number of parents that donate their children's tissue to de-

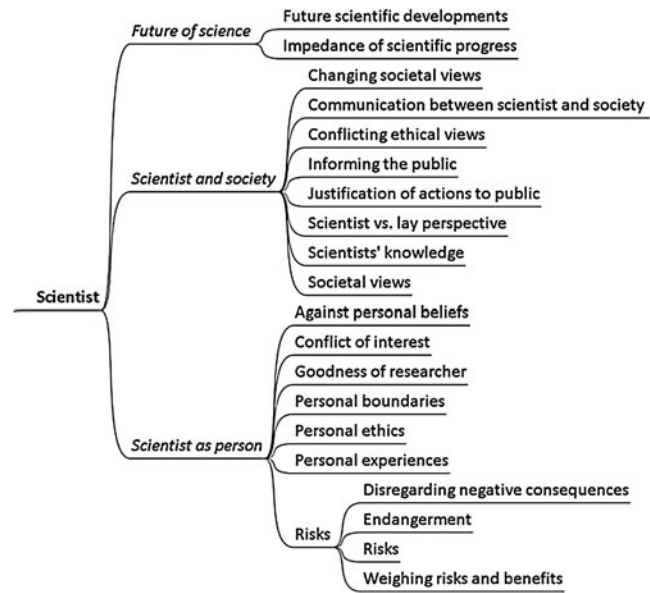


FIG. 3. Themes and codes for cluster "Scientist."

crease. They conjectured a decrease in number of donated tissues might seriously impede scientific progress. One participant, a university teacher, used the analogy of using animals to benefit human beings through research: "[N]ot everyone understands the implications of not giving away tissue samples for research. I would like to [use] the example of my teaching where I say 'animal trials' and students stand up and say 'no, why do you use animals? [...] we're totally against the use of any animals for anything.' And I say, 'Okay, please sign this paper, we will not use any of the treatments that have been developed using animals on you and your family.' They say, 'Uh oh, no, no, I'm [in favor of] animal...use of animals,' so the implications of not being able to use human tissue in research means that you don't have a cure for diseases and the coupling there is not maybe obvious for people. It's not even obvious for my university students."

Scientist and society. The relationship between a scientist and society, especially the role of communication, was discussed extensively. The risk of popular media picking up wildly negative stories about certain technologies was viewed by all as a real threat. According to the participants, the influence of the media on popular opinion about technology should not be underestimated. Therefore, scientists should tell the public about their work, although explaining the details of the tissue engineering process to a largely lay audience remains a challenge.

One participant described the responsibility of a scientist as follows: "[S]cientists tend to only see the good side of stem cell biology, and we often forget that there is a general public which has an opinion about the consequences of different research and scientists have a tendency to think; oh, this...this works for this particular application while there's a huge amount of consequences that maybe we're not thinking about. [...] Before you jump on a new train you have to test that it's safe and that, for instance, if we use embryonic stem cells there are all sort of different cancers and new diseases

that can be introduced. Maybe not right away, but maybe in 50 years, and this is gonna be a new generation of kids that we have helped survive, but that will develop terrible diseases in the future. [...] So, I think it's sort of why we're sitting here and discussing this because we need to be aware that the general public has an opinion and we carry a very strong responsibility to make sure that we sort of think twice before we just..."

Scientist as person. With the talk of bad research, public mistrust and misinformation, one of the participants was quick to add the following: "I think we should state again that the researchers are, most of the researchers are on the good side, and that they really want to develop treatments, and that they do not want to create Franksteins or make money out of it and therefore it's not such an ethical issue to give the consent to use the tissue for research purposes, at least in my view. [...] If it comes to companies that are using the tissues, this is probably...or definitely different, and if it comes to induced pluripotent stem cell lines that are being created from differentiated cells that is also a different issue. But if you do our standard work that we all do now, I think we are still on the good side and we could even show the donors or the people that gave the consent what has been done with the tissue and in which direction the research is going."

In talking about how they reached a moral judgment of a certain act or technology, the participants indicated that different personal factors influence their judgments of right and wrong, and their willingness to work with certain matters or perform certain actions. One of these factors seemed to be personal experience with a disease that was potentially treatable with the technology at hand. This might make a scientist more likely to judge the technology favorably. Other factors mentioned included the way they were raised by their parents, and possible religious influences. In the end, participants seemed to view ethical judgments on the acceptability of a certain conduct or technology as incredibly personal, as one person said: "[F]or me there's no right or wrong, if [other participant X] says her opinion, then her opinion is as good as my opinion."

Discussion

On the basis of the results of two previous rounds of questionnaires, two categories of issues were discussed in two focus group discussions: donation and source of cells. The results of the discussion were divided into three clusters: Tissue, Donor, and Scientist. Where the former two roughly coincide with the two groups of issues that were the result of the previous Delphi rounds, a third, entirely new, subject was discussed by both groups: the role of the scientist in the tissue engineering process.

When comparing our results to discussions in the literature on the same topics, several similarities become apparent. For instance, like our participants, articles that discuss informed consent of tissue donors stress the importance of thorough information about future use of their material⁹⁻¹⁹ and protecting the privacy of the donor through anonymity.^{10,12-14,17-21} In our study, we learned of the difficulties that would arise while striving for these ideals in practice, as they were pointed out by our participants.

In surveying the arguments of the focus group participants, one matter is striking. Their way of arguing their case is very personal and subjective: in answering a question, their responses take the form of "if I were in that situation, I would..." or "if that were my child, I..." Additionally, participants' answers generally display a consequentialist manner of reasoning: in assessing a situation, the majority of the participants look to the consequences of an act as the criterion for deeming it morally right or wrong. One example is the use of embryonic stem cells and the ensuing discussion of what is considered human life. The ethical literature on the topic generally argues the case in terms of principles (e.g., sanctity of life and human dignity).²²⁻²⁶ However, in these focus groups, the discussion came down to the comparison of different manners of obtaining tissue and their possible negative consequences, with those consequences informing the eventual moral judgment. A similar thing is apparent in the discussion of paid donation. Where the literature, while also discussing undesirable consequences, argues mostly in terms of violating human dignity,^{18,27-32} the discussion in our focus groups solely focused on the undesirable situations paid donation might result in.

As is known from literature on teaching ethics, certain tendencies are apparent when non-ethicists discuss ethics, most notably skepticism (the belief that ethics has no right or wrong answers) and subjectivism (the belief that ethics is whatever any person feels is right).^{33,34} From time to time, both are also noticeable in our participants' reasoning. As became apparent in the focus group discussions, the participants seem very aware of their personal responsibilities both toward the scientific community and society at large. However, to meet these responsibilities in the complex setting of scientific research in research groups or competitive enterprises, skepticism and subjectivism are insufficient. Working with a group of people toward a common goal, some sort of intersubjective truth or norm is needed, one that transcends mere personal opinion or preference. These ethical norms in research help scientists to coordinate their actions and to establish and maintain the public's trust of the discipline.³⁵

Because the focus groups were part of a larger Delphi study and were preceded by two rounds of questionnaires, the participants were familiar with each other and the study in question. Therefore, during the focus group meetings relatively little time was needed to familiarize the participants with the process, as a cognitive process had already been set in motion.

Our population consisted of a diverse group of tissue engineering professionals: participants were involved in different types of fundamental research, and many different countries, nationalities, occupations, and institutions were represented. The views of tissue engineering experts outside of the EuroSTEC project, as well as those of ethicists and patients, were lacking from this study. To obtain an even richer overview of the ethical aspects of tissue engineering, it is our explicit intention to extend the target population of future empirical research to include these other groups.

Ethics of tissue engineering and regenerative medicine is still a relatively small field. This study is the first to feature qualitative research concerning tissue engineering professionals' views on ethical aspects of preclinical research in tissue engineering. Although the participants in this study were recruited from one specific project, the relevance of our

results need not to be limited to this project. Numerous parallels can be drawn between the project at hand and any other preclinical study in the field of tissue engineering. Therefore, we believe that our study will be of relevance to fundamental research in tissue engineering in general.

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Disclosure Statement

No competing financial interests exist.

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